

**I. Preliminary Remarks**

This response is timely filed, as it accompanied by a petition for extension of time to file in the first month. Should the Patent Office determine that additional fees are required for consideration of this response, permission is hereby granted to charge such fees to Deposit Account No. 03-3975 (081691-0284960). Any overpayments should be credited to the same account.

**II. Restriction**

Citing 35 U.S.C. § 121, the examiner alleged that claims 28-31 and 40-50 are directed to patentability distinct species of the claimed invention.

- I. a specific fish serine proteinase ( trypsin I, II, or III); and
- II. a specific disease (pain, acute inflammation, chronic inflammation, arthritis, inflamed joints, bursitis, osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, septic arthritis, fibromyalgia, systemic lupus erythematosus, phlebitis, tendinitis, rash, psoriasis, acne, eczema, facial seborrheic eczema, eczema of the hands, face or neck, foreskin infections, athlete's foot, fistulae infections, infected topical ulcers, navel infections in newborns, wrinkles, scars, keloids, boils, warts and allergic itch, hemorrhoids, wounds, wound infections, wounds from burns or a fungal infection).

**III. Election**

The applicant hereby elects, with traverse in part, trypsin I from Atlantic Cod as the specific fish serine proteinase and arthritis as the specific disease.

**IV. Traversal Arguments—Restriction of the Markush Serine Proteinase Claims is Improper**

The restriction requirement includes an allegation that claims 28-31 and 40-50 contain three distinct species to either trypsin I, II, or III from Atlantic cod without reason. The MPEP provides a two-part test for assessing the propriety of restricting Markush Groups:

Since the decisions of *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included with a Markush group (1) **share a common unity**,

**and (2) share a substantial structural feature** disclosed as being essential to that utility.

See MPEP § 803.02 (Emphasis added)

The trypsin enzymes I, II, or III within claims 28-31 and 40-50 are unified inventions according to MPEP § 803.02. The Markush groups of the trypsin enzymes I, II, or III share a common utility of effectively removing or inactivating certain cell-surface adhesion molecules, bacterial enterotoxins, cytokines, inflammatory mediators, and matrix metalloproteinases (MMPs) such as CD4, CD8, CD54 (ICAM-1), CD31, CD62L, CD102 (ICAM-2), CD11a/CD18, TNF-alfa, IL-1, and MMP-9 without affecting cell viability. This common utility exists amongst trypsin enzymes I, II, or III because the amino acid sequence of the three isozymes of cod trypsin share a strong amino acid sequence homology and molecular mass (24 kDa) with each other (see page 12, lines 21-32). Due to this high homology and identical molecular mass, these trypsin enzymes can be considered species of the genus fish serine proteinase.

In addition, as set forth below, the MPEP's guidelines in §§ 806.03 and 806.04 involving genus-species issues, also necessitates withdrawal of the restriction. The Patent Office's own rules require that "a reasonable number of species may still be claimed in one application....." (See MPEP § 806.04(a)), citing 37 C.F.R. § 1.141). Accordingly, the applicant respectfully requests that the restriction requirement, with respect to the trypsin enzymes I, II, or III, be withdrawn and all three proteases be examined simultaneously.

**V. Conclusion**

In view of the foregoing, the applicant submits that they have fully and properly responded to the outstanding restriction requirement. Should the examiner have any questions or comments regarding this response or the application, the examiner is invited to contact the undersigned at the number indicated.

Respectfully submitted,

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